JUN 2 1 2002

K013814

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SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant:	ConvaTec, A Division of E.R. Squibb and Sons, L.L.C. 200 Headquarters Park Drive, Skillman, NJ 08558
Contact:	Demetrios Kydonieus, Regulatory Affairs (908) 904-2537
Device:	Absorbent Antimicrobial Wound Dressing
Substantially Equivalent Device	Acticoat™ Silver Coated Dressing

The purpose of this 510(k) Premarket Notification is to request clearance to market Absorbent Antimicrobial Wound Dressing.

Absorbent Antimicrobial Wound Dressing is composed of sodium carboxymethylcellulose and ionic silver. In contact with wound exudate, the highly absorbent dressing creates a soft, cohesive gel that forms an intimate contact with the wound surface and maintains a moist wound-healing environment.

For over-the-counter use, Absorbent Antimicrobial Wound Dressing may be used for: minor abrasions, lacerations, minor cuts, minor scalds and burns.

Under the supervision of a health care professional, Absorbent Antimicrobial Wound Dressing is an effective barrier to bacterial penetration, which may help reduce infection in partial thickness (second degree) burns, diabetic foot ulcers, leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology) and pressure ulcers/sores (partial & full thickness), surgical wounds left to heal by secondary intent, traumatic wounds, wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided and oncology wounds with exudate such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma.

Absorbent Antimicrobial Wound Dressing may be used on minimally exuding, non-exuding and dry wounds, as stated in the DIRECTIONS FOR USE

Absorbent Antimicrobial Wound Dressing is contraindicated for use on individuals who are sensitive to or who have had an allergic reaction to the dressing or its components.

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Absorbent Antimicrobial Wound Dressing is substantially equivalent to Acticoat™ Silver Coated Wound Dressing. Both dressings are indicated for acute and chronic wounds. Absorbent Antimicrobial Wound Dressing is similar to Acticoat™ Silver Coated Wound Dressing where both are of a similar composition consisting of silver and absorbent padding to absorb wound exudate, and create a moist wound environment supportive of the healing process. Comparative bench testing was conducted on Acticoat™ Silver Coated Wound Dressing and Absorbent Antimicrobial Wound Dressing.

Absorbent Antimicrobial Wound Dressing has been subject to biocompatibility testing. The results of this testing show that Absorbent Antimicrobial Wound Dressing has passed toxicity and safety tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2002

Mr. Demetrios Kydonieus
Director, Regulatory Affairs
ConvaTec
200 Headquarters Park Drive
Skillman, NJ 08558

Re: K013814
Trade/Device Name: Absorbent Antimicrobial Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 15, 2002
Received: April 16, 2002

Dear Mr. Kydonieus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013814

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Not Known

Device Name: Absorbent Antimicrobial Wound Dressing

Indications for Use:

For over-the-counter use, Absorbent Antimicrobial Wound Dressing may be used for minor abrasions, lacerations, minor cuts, minor scalds and burns.

Under the supervision of a health care professional, Absorbent Antimicrobial Wound Dressing is an effective barrier to bacterial penetration, which may help reduce infection in partial thickness (second degree) burns, diabetic foot ulcers, leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology) and pressure ulcers/sores (partial & full thickness), surgical wounds left to heal by secondary intent, traumatic wounds, wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided and oncology wounds with exudate such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma and angiosarcoma.

Absorbent Antimicrobial Wound Dressing may be used on minimally exuding, non-exuding and dry wounds as stated in the DIRECTIONS FOR USE.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Perscription Use X
(Per 21CFR 801.109)

OR

Over the Counter Use X
(Optimal Format 2-96)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013814